UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/397,110	09/16/1999	NORMAN JAMES MOORE		8332

7590 11/06/2002

MARY HELEN SEARS
THE M H SEARS LAW FIRM CHARTERED
910 SEVENTEENTH STREET NW
SUITE 800
WASHINGTON, DC 20006

EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/06/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/397,110	Applicant(s) Moore et al
	Examiner Portner	Art Unit 1645

-- Th MAILING DATE f this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 15, 2002* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under ***Ex parte Quayle***, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9 and 33-54* is/are pending in the application.

4a) Of the above, claim(s) *1-9* is/are withdrawn from consideration.

5) ☒ Claim(s) *33-40 and 42* is/are allowed.

6) ☒ Claim(s) *50-54* is/are rejected.

7) ☒ Claim(s) *43-49* is/are objected to.

8) ☒ Claims *1-9 and 33-54* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-9 and 33-54 are pending

Claims 1-9 are non-elected claims..

Claims 10-32 and 41 have been canceled.

Claims 33-40 and 42-54 have been amended.

Allowable Subject Matter

1. Claims 33-40, 42 define allowable subject matter, as the prior art of record does not teach nor reasonably suggest the claimed combination of methods steps for detecting Streptococcus pneumoniae in a liquid sample.

Claim Objections/Rejections Withdrawn

2. Claim 50 objected to because of the following informalities in light of the word "containg" amended to recite --containing--.

3. Claim 33 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps (See MPEP § 2172.01) in light of the claim having been amended to recite specific methods steps for detecting S.pneumoniae and/C-polysaccharide.

4. Claim 33 rejected under 35 U.S.C. 112, second paragraph for reciting in section e), line six recites the phase "which may in part be conjugated to a tag", in light of the clarifying claim limitations.

5. Claims 33-48 rejected under 35 U.S.C. 112, second paragraph for reciting term "essentially comprise", in light of the deletion of the term from the claims.

6. Claim 34 rejected under 35 U.S.C. 112, second paragraph, for depending from claim 32 which has been canceled, in light of the amendment of claim 34 to depend from claim 33.

7. Claim 37 rejected under 35 U.S.C. 112, second paragraph, for reciting the phrase "fluid sample" in light of the amendment of the claims to provide antecedent basis for the term "liquid".

8. Claims 40 and 49 rejected under 35 U.S.C. 112, second paragraph, for reciting the phase "developed meningitis", in light of the amendment to define the patient as being suspected of having meningitis.

9. Claim 41 rejected under 35 U.S.C. 112, second paragraph, in light of claim 41 having been canceled.

10. Claim 42 rejected under 35 U.S.C. 112, second paragraph, in light of claim 42 having been amended to depend from claim 33 which now recites the utilization of a solid surface, and claim 42 further limits claim 33 by defining the solid surface step (e) to be an immunochromatographic surface and process.

11. Claim 45 rejected under 35 U.S.C. 112, second paragraph, in light of claim 45 having been amended to depend from claim 44.

12. Claims 46,48-49 rejected under 35 U.S.C. 112, second paragraph, in light of claim 45 having been amended to depend from claim 44.

13. Claim 50 rejected under 35 U.S.C. 112, second paragraph, section b) for reciting the phrase "for viewing color changes", in light of the claim having been amended to define the change to be the presence or absence of a labeling agent.

14. Claim 51 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of claim 50 to clarify the labeling agent to produce a color and claim 51 defines a specific labeling agent.

15. Claims 52-54 rejected under 35 U.S.C. 112, second paragraph, in light of the amendment of claims 52-54 to depend from claim 50, and not claim 49.

16. Claim 52, section c) rejected under 35 U.S.C. 112, second paragraph for reciting the phrase "entrained conjugate" in light of the phrase having been deleted from claim 52.

17. Claims 50-51(Streptococcus pneumoniae) ~~are~~ rejected under 35 U.S.C. 102(b) as being anticipated by Imrich (US Pat. 5,415,994) in light of Gribnau et al (US Pat. 4,373,932, incorporated by reference in Imrich), in light of the amendment limiting the claims to the detection of S.pneumoniae cell wall C-polysaccharide.

18. Claims 52-54 ~~are~~ rejected under 35 U.S.C. 102(b) as being anticipated by Imrich (US Pat. 5,415,994), in light of the amendment limiting the claims to the detection of S.pneumoniae cell wall C-polysaccharide.

19. Claims 52-54 ~~are~~ rejected under 35 U.S.C. 102(b) as being anticipated by May et al, in light of the amendment limiting the claims to the detection of S.pneumoniae cell wall C-polysaccharide.

20. Claims 52-54 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01, in light of the amendment of the claims to recite the phrase "bibulous material contained in the ICT device of claim 50" which is being read to comprise first and second antibodies, specifically C-polysaccharide antibodies and first and second zone.

Rejections Maintained

21. Claim 43, step (e), rejected under 35 U.S.C. 112, second paragraph for reciting non-corresponding methods steps and not further limiting claim 33 from which it depends, because claim 43 further comprises additional methods steps or changes the methods steps all together, for reasons of record in paper number 9, paragraph 6, page 6.

22. Claim 52, section b) rejected under 35 U.S.C. 112, paragraph for reciting the phrase "said test strip" for reasons of record in paper number 9, paragraph 6, on page 7.

23. Claims 50-51 and 52-54(C-polysaccharide antigen species) are rejected under 35 U.S.C. 103(a), as previously applied to claims 50-51, as being unpatentable over Imrich (US Pat. 5,415,994) in light of Gribnau et al (US Pat. 4,373,932, incorporated by reference in Imrich, col. 5, line 37) in view of Krook et al (1987), for reasons of record in paper number 9, paragraph 13.

24. Claims 50-51 and 52-54 (Canceled) (C-polysaccharide antigen species) are rejected under 35 U.S.C. 103(a), as previously applied to claims 50-51, as being unpatentable over May et al (WO88/08534) in view of Krook et al (1987), , for reasons of record in paper number 9, paragraph 14.

Response to Arguments

25. The rejection of claim 43 under 35 U.S.C. 112, second paragraph is traversed on the grounds that claim 43 has been "extensively revised and recites details of a preferred ICT process.

26. It is the position of the examiner that while claim 43 has been amended, the claim still depends from claim 33 which recites the steps of:

contacting, further contacting and detecting,

while claim 43 recites the methods steps of:

contacting, allowing, allowing and within.

Dependent claim 43 should recite the phrase --further comprising-- or a --wherein-- statement that further limits one of the steps of claim 33. Claim 43 sets for methods steps which claim 33 does not provide antecedent basis and intends to substitute the method steps recited in claim 43 for the methods step of claim 33. The "within" step Claim 43, section d), could be made clear by amending the claim to recite the phrase --detecting within-- or --observing within---.

27. The rejection of claim 52, section b) under 35 U.S.C. 112, paragraph for reciting the phrase "said test strip" is traversed on the grounds that claim 50 imparts the antecedents that are missing.

28. It is the position of the examiner that the phrase "test strip" is not recited in claim 50; amendment of claim 50 to recite --test strip comprising a bibulous material-- could obviate this rejection.

29. The rejection of claims 50-51 and 52-54(C-polysaccharide antigen species) under 35 U.S.C. 103(a), as previously applied to claims 50-51, as being unpatentable over Imrich in light of Gribnau et al in view of Krook et al (1987) is traversed on the grounds that:

" Imrich teaches nothing about any antibody for an antigen of Streptococcus pneumoniae."

30. It is the position of the examiner that Imrich et al teaches an ICT device called a lateral flow device, which will specifically detect Group A streptococcus specific antigens (see col. 4, lines 19-20), specifically teaches the importance of detecting Streptococcus pneumonia (see col. 7, line 2), and claims a device that comprises immunoglobulin specific for Streptococcus pneumoniae (see claim 15).

In response to applicant's arguments against the references individually (Imrich et al alone), one cannot show nonobviousness by attacking references individually where the

rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

31. The guidance and teaching of Imrich in light of Gribnau is traversed on the grounds that "Imrich, gives no information except to suggest that the antibodies for an antigen of any of the bacteria are discussed by Imrich could be gold-labeled".

32. It is the position of the examiner that Imrich et al teaches immunoglobulin particulate labels, to include gold-labeled antibodies, that have been successfully made and used in immunoassay methods. The rejection was based upon the guidance and teachings presented in a US Patent which was incorporated by reference, thus constructive reduction to practice was achieved through this teaching.

33. Imrich et al is traversed by asserting that the antibodies that are specific for Streptococcus pneumoniae does "not lead one to an operable, useful test of high sensitivity and specificity for detecting an antigen characteristic of Streptococcus pneumoniae."

34. It is the position of the examiner that the instantly claimed device compositions that comprise S.pneumoniae specific antibodies and a method of using the device, do not require the antibodies to be of any specific sensitivity or specificity, but must only be "specific (instant claim 50, paragraph a) ". Clearly Imrich et al teach antigen specific antibodies of S.pneumoniae.

35. Gribnau et al is asserted to teach away for the utilization of gold metal sols.

36. It is the position of the examiner that Imrich et al teaches the utilization of metal sols (see Imrich col. 5, lines 33-34) as a label, and Gribnau et al was cited for teaching a specific type of sol and dyes and a method of attaching the particulate labels to antibodies. Gribnau et al was not cited for what it taught with respect to immunoassay methods, or specific antibodies, but for teaching gold sols as antibody labels, as well as teaching methods of attaching them to antibodies.

37. Krook et al is traversed for not teaching an immunochromatographic assay.

38. It is the position of the examiner that Imrich et al teach an immunochromatographic assay. Krook et al was cited for teaching S.pneumoniae specific antibodies, both affinity purified polyclonal antibodies and a monoclonal antibody. The antibodies were shown to be specific and sensitive for detecting specific to S. pneumoniae C-polysaccharide antigen in a two antibody immunoassay for detecting S. pneumoniae C-polysaccharide in a patient sample. The incorporation of the antibodies of Krook et al into the device of Imrich would provide a means for detecting Streptococcus pneumoniae, a human pathogen, and/or C-polysaccharide antigen, an antigen shown to be associated with infection in a rapid(see Imrich et al, col. 6, line 68 and col. 7, lines 2-10) immunoassay method.

39. Sjogren is asserted to have been used in the rejection of the claims under 35 U.S.C. 103.

40. It is the position of the examiner that Sjorgen et al was not applied to the claims.

41. The rejection of claims 50-51, 52-54 (C-polysaccharide antigen species) under 35 U.S.C. 103(a) as being unpatentable over May et al (WO88/08534) in view of Krook et al (1987) is traversed on the grounds that: "May et al suggest no assay for any antigen of Streptococcus pneumoniae."

42. It is the position of the examiner that May et al teach the detection of Streptococcus specific antigens (see May et al, page 17, line 10) , Streptococcus serotypes and antigens of Streptococcal groups A, B, C and D (see May et al, page 19, lines 6-12). Clearly May et al view Streptococcus pathogens as an important analyte to be detected.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

43. Krook et al is traversed on the grounds that the monoclonal and polyclonal antibodies are not "Applicant's purified antibodies".

44. It is the position of the examiner that the claimed antibodies are specific to the cell wall C-polysaccharide of Streptococcus pneumoniae (see claim 50, section a) as are the antibodies of Krook et al. The antibodies of Krook et al are equivalent to the recited antibodies of the claims that are specific for the cell wall C-polysaccharide of Streptococcus pneumoniae antigen. It would have been obvious to the person of ordinary skill in the art at the time the invention was

made to modify the device of May et al to utilize antibodies specific for Streptococcus C-polysaccharide antigen of Krook et al because Krook et al teaches Streptococcus antibodies able to detect the presence of Streptococcus pneumoniae C-polysaccharide antigen in a biological sample, May et al teaches the importance of detecting Streptococcus antigen to assist in diagnosis of infection (see page 17, line 10, and lines 16-18) and the device of May et al provides means for a rapid immunoassay format that minimizes operator performance time (see May, page 2, lines 6-7, 10 minutes or less and page 2, lines 33-34).

New Claims Limitations/New Grounds of Rejection

Claim Objections

45. Claims 43-49 are objected to under 37 CFR 1.75© as being in improper form because a multiple dependent claim must depend from a previous claim in the alternative; claim 43 depends from claims 42 and 33 simultaneously which is improper. See MPEP § 608.01(n). Accordingly, the claims 43-49 have not been further treated on the merits.

46. The examiner noted at page 16, paragraph 4, Applicant makes the statement "It is again noted in this regard that Applicant's do not contend they invented this device per se, but only point out that they have chosen it for their commercial, FDA-approved embodiment." If the device claimed (claims 50-51) has not been invention by Applicant, what is the newly invented portion of the claims? Is what is claimed intended to be at type of Jepsen claim?

Conclusion

47. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

48. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242. The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
October 28, 2002

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER